

(i)] applying to said preparation of one or more digestive enzymes at least [two] one stabilizing process[es selected from the group consisting of

- (a) reducing the residual solvent content of said preparation of one or more digestive enzymes,
- (b) reducing the temperature of said preparation of one or more digestive enzymes, and
- (c) adding at least one stabilizer to said preparation of one or more digestive enzymes; and

(ii) irradiating said preparation of one or more digestive enzymes with a suitable radiation at an effective rate for a time effective to sterilize said preparation of one or more digestive enzymes] comprises applying to said preparation of one or more digestive enzymes at least two processes, wherein said at least two stabilizing processes are together effective to protect said preparation of one or more digestive enzymes from said radiation and further wherein said at least two stabilizing processes may be performed in any order.

7. (Amended) The method according to claim [3,] 5 or 6, wherein said solvent is water.

9. (Amended) The method according to claim [3,] 5 or 6, wherein said solvent is an organic solvent.

10. (Amended) The method according to claim [3,] 5 or 6, wherein said preparation of one or more digestive enzymes is suspended in an organic solvent following reduction of said residual solvent content.
11. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said effective rate is not more than about 3.0 kGy/hour.
12. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said effective rate is not more than about 2.0 kGy/hr.
13. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said effective rate is not more than about 1.0 kGy/hr.
14. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said effective rate is not more than about 0.3 kGy/hr.
15. (Amended) The method according to claim [2, 3, 4,] 5 or 6, wherein said effective rate is more than about 3.0 kGy/hour.

16. (Amended) The method according to claim [2, 3, 4,] 5 or 6, wherein said effective rate is at least about 6.0 kGy/hour.

17. (Amended) The method according to claim [2, 3, 4,] 5 or 6, wherein said effective rate is at least about 18.0 kGy/hour.

18. (Amended) The method according to claim [2, 3, 4,] 5 or 6, wherein said effective rate is at least about 30.0 kGy/hour.

19. (Amended) The method according to claim [2, 3, 4,] 5 or 6, wherein said effective rate is at least about 45 kGy/hour.

20. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said preparation of one or more digestive enzymes is maintained in a low oxygen atmosphere.

21. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said preparation of one or more digestive enzymes is maintained in an atmosphere comprising at least one noble gas.

23. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said preparation of one or more digestive enzymes is maintained in a vacuum.

24. (Amended) The method according to claim [3,] 5 or 6, wherein said residual solvent content is reduced by a method selected from the group consisting of lyophilization, drying, concentration, addition of solute, evaporation, chemical extraction, spray-drying and vitrification.

25. (Amended) The method according to claim [3,] 5 or 6, wherein said residual solvent content is less than about 15%.

26. (Amended) The method according to claim [3,] 5 or 6, wherein said residual solvent content is less than about 10%.

27. (Amended) The method according to claim [3,] 5 or 6, wherein said residual solvent content is less than about 3%.

28. (Amended) The method according to claim [3,] 5 or 6, wherein said residual solvent content is less than about 2%.

29. (Amended) The method according to claim [3,] 5 or 6, wherein said residual solvent content is less than about 1%.

30. (Amended) The method according to claim [3,] 5 or 6, wherein said residual solvent content is less than about 0.5%.

31. (Amended) The method according to claim [3,] 5 or 6, wherein said residual solvent content is less than about 0.08%.

32. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein at least one sensitizer is added to said preparation of one or more digestive enzymes prior to said step of irradiating said preparation of one or more digestive enzymes.

33. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said preparation of one or more digestive enzymes contains at least one biological contaminant or pathogen selected from the group consisting of viruses, bacteria, yeasts, molds, fungi, prions or similar agents responsible, alone or in combination, for TSEs and single or multicellular parasites.

34. (Amended) The method according to claim [2,] 5 or 6, wherein said at least one stabilizer is an antioxidant.

35. (Amended) The method according to claim [2,] 5 or 6, wherein said at least one stabilizer is a free radical scavenger.

36. (Amended) The method according to claim [2,] 5 or 6, wherein said at least one stabilizer is a combination stabilizer.

37. (Amended) The method according to claim [2,] 5 or 6, wherein said at least one stabilizer is a ligand.

39. (Amended) The method according to claim [2,] 5 or 6, wherein said at least one stabilizer reduces damage due to reactive oxygen species.

40. (Amended) The method according to claim [2,] 5 or 6, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof; glutathione; 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate and mixtures of two or more thereof.

42. (Amended) The method according to claim [2,] 5 or 6, wherein said at least one stabilizer is a dipeptide stabilizer.

44. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said radiation is corpuscular radiation or electromagnetic radiation, or a mixture thereof.

47. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said radiation is E-beam radiation.

48. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said radiation is visible light.

49. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said radiation is ultraviolet light.

50. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said radiation is x-ray radiation.

51. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said radiation is polychromatic visible light.

52. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said radiation is infrared

53. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said radiation is a combination of one or more wavelengths of visible and ultraviolet light.

54. (Amended) The method according to claim [1, 2, 3,] 5 or 6, wherein said irradiation is conducted at ambient temperature.

55. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said irradiation is conducted at a temperature below ambient temperature.

56. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said irradiation is conducted below the freezing point of said preparation of one or more digestive enzymes.

57. (Amended) The method according to claim [1, 2, 3, 4,] 5 or 6, wherein said irradiation is conducted below the eutectic point of said preparation of one or more digestive enzymes.

58. (Amended) The method according to claim [1, 2, 3,] 5 or 6, wherein said irradiation is conducted at a temperature above ambient temperature.

Clean Set of Amended Claims

a1 6. (Amended) The method according to claim 5, wherein said applying to said preparation of one or more digestive enzymes at least one stabilizing process comprises applying to said preparation of one or more digestive enzymes at least two processes, wherein said at least two stabilizing processes are together effective to protect said preparation of one or more digestive enzymes from said radiation and further wherein said at least two stabilizing processes may be performed in any order.

7. (Amended) The method according to claim 5 or 6, wherein said solvent is water.

9. (Amended) The method according to claim 5 or 6, wherein said solvent is an organic solvent.

a2 10. (Amended) The method according to claim 5 or 6, wherein said preparation of one or more digestive enzymes is suspended in an organic solvent following reduction of said residual solvent content.

11. (Amended) The method according to claim 5 or 6, wherein said effective rate is not more than about 3.0 kGy/hour.

12. (Amended) The method according to claim 5 or 6, wherein said effective rate is not more than about 2.0 kGy/hr.

13. (Amended) The method according to claim 5 or 6, wherein said effective rate is not more than about 1.0 kGy/hr.

14. (Amended) The method according to claim 5 or 6, wherein said effective rate is not more than about 0.3 kGy/hr.

15. (Amended) The method according to claim 5 or 6, wherein said effective rate is more than about 3.0 kGy/hour.

a² 16. (Amended) The method according to claim 5 or 6, wherein said effective rate is at least about 6.0 kGy/hour.

17. (Amended) The method according to claim 5 or 6, wherein said effective rate is at least about 18.0 kGy/hour.

18. (Amended) The method according to claim 5 or 6, wherein said effective rate is at least about 30.0 kGy/hour.

19. (Amended) The method according to claim 5 or 6, wherein said effective rate is at least about 45 kGy/hour.

20. (Amended) The method according to claim 5 or 6, wherein said preparation of one or more digestive enzymes is maintained in a low oxygen atmosphere.

a² 21. (Amended) The method according to claim 5 or 6, wherein said preparation of one or more digestive enzymes is maintained in an atmosphere comprising at least one noble gas.

23. (Amended) The method according to claim 5 or 6, wherein said preparation of one or more digestive enzymes is maintained in a vacuum.

a³ 24. (Amended) The method according to claim 5 or 6, wherein said residual solvent content is reduced by a method selected from the group consisting of lyophilization, drying, concentration, addition of solute, evaporation, chemical extraction, spray-drying and vitrification.

25. (Amended) The method according to claim 5 or 6, wherein said residual solvent content is less than about 15%.

26. (Amended) The method according to claim 5 or 6, wherein said residual solvent content is less than about 10%.

27. (Amended) The method according to claim 5 or 6, wherein said residual solvent content is less than about 3%.

28. (Amended) The method according to claim 5 or 6, wherein said residual solvent content is less than about 2%.

29. (Amended) The method according to claim 5 or 6, wherein said residual solvent content is less than about 1%.

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30. (Amended) The method according to claim 5 or 6, wherein said residual solvent content is less than about 0.5%.

31. (Amended) The method according to claim 5 or 6, wherein said residual solvent content is less than about 0.08%.

32. (Amended) The method according to claim 5 or 6, wherein at least one sensitizer is added to said preparation of one or more digestive enzymes prior to said step of irradiating said preparation of one or more digestive enzymes.

33. (Amended) The method according to claim 5 or 6, wherein said preparation of one or more digestive enzymes contains at least one biological contaminant or pathogen selected from the group consisting of viruses, bacteria, yeasts, molds, fungi, prions or similar agents responsible, alone or in combination, for TSEs and single or multicellular parasites.

34. (Amended) The method according to claim 5 or 6, wherein said at least one stabilizer is an antioxidant.

35. (Amended) The method according to claim 5 or 6, wherein said at least one stabilizer is a free radical scavenger.

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36. (Amended) The method according to claim 5 or 6, wherein said at least one stabilizer is a combination stabilizer.

37. (Amended) The method according to claim 5 or 6, wherein said at least one stabilizer is a ligand.

39. (Amended) The method according to claim 5 or 6, wherein said at least one stabilizer reduces damage due to reactive oxygen species.

a4 40. (Amended) The method according to claim 5 or 6, wherein said at least one stabilizer is selected from the group consisting of: ascorbic acid or a salt or ester thereof; glutathione; 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid; uric acid or a salt or ester thereof; methionine; histidine; N-acetyl cysteine; lipoic acid; sodium formaldehyde sulfoxylate; gallic acid or a derivative thereof; propyl gallate and mixtures of two or more thereof.

a5 42. (Amended) The method according to claim 5 or 6, wherein said at least one stabilizer is a dipeptide stabilizer.

a6 44. (Amended) The method according to claim 5 or 6, wherein said radiation is corpuscular radiation or electromagnetic radiation, or a mixture thereof.

47. (Amended) The method according to claim 5 or 6, wherein said radiation is E-beam radiation.

a7 48. (Amended) The method according to claim 5 or 6, wherein said radiation is visible light.

49. (Amended) The method according to claim 5 or 6, wherein said radiation is ultraviolet light.

50. (Amended) The method according to claim 5 or 6, wherein said radiation is x-ray radiation.

51. (Amended) The method according to claim 5 or 6, wherein said radiation is polychromatic visible light.

52. (Amended) The method according to claim 5 or 6, wherein said radiation is infrared

53. (Amended) The method according to claim 5 or 6, wherein said radiation is a combination of one or more wavelengths of visible and ultraviolet light.

54. (Amended) The method according to claim 5 or 6, wherein said irradiation is conducted at ambient temperature.

55. (Amended) The method according to claim 5 or 6, wherein said irradiation is conducted at a temperature below ambient temperature.

56. (Amended) The method according to claim 5 or 6, wherein said irradiation is conducted below the freezing point of said preparation of one or more digestive enzymes.

57. (Amended) The method according to claim 5 or 6, wherein said irradiation is conducted below the eutectic point of said preparation of one or more digestive enzymes.

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cont 58. (Amended) The method according to claim 5 or 6, wherein said irradiation is conducted at a temperature above ambient temperature.
